

Technical Project Lead (TPL) Review:

SE0014544 - SE0014548

SE0014544: Husky Fine Cut Wintergreen	
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ¹	(b) (4)
Characterizing Flavor	Wintergreen
SE0014545: Husky Long Cut Straight	
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ²	(b) (4)
Characterizing Flavor	None
SE0014546: Husky Long Cut Mint	
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ²	(b) (4)
Characterizing Flavor	Mint
SE0014547: Husky Long Cut Natural	
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ²	(b) (4)
Characterizing Flavor	None
SE0014548: Husky Fine Cut Natural	
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ¹	(b) (4)
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	US Smokeless Tobacco Company
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

¹ The applicant states that the new and predicate tobacco products contain a tobacco base comprised of (b) (4) and (b) (4)

² The applicant states that the new and predicate tobacco products contain a tobacco base comprised of (b) (4) and (b) (4)

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.05.15 13:41:43 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Director
Division of Product Science

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2018.05.15 13:44:27 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0014544: Husky Fine Cut Wintergreen	
Product Name	Husky Fine Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ¹	(b) (4)
Characterizing Flavor	Wintergreen
SE0014545: Husky Long Cut Straight	
Product Name	Husky Long Cut Straight
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ²	(b) (4)
Characterizing Flavor	None
SE0014546: Husky Long Cut Mint	
Product Name	Husky Long Cut Mint
Package Type	Plastic Can with Lid
Package Quantity	34.02 g
Tobacco Cut Size ²	(b) (4)
Characterizing Flavor	Mint
SE0014547: Husky Long Cut Natural	
Product Name	Husky Long Cut Natural
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ²	(b) (4)
Characterizing Flavor	None
SE0014548: Husky Fine Cut Natural	
Product Name	Husky Fine Cut Natural
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size ¹	(b) (4)
Characterizing Flavor	None

The predicate tobacco products are loose moist snuff smokeless tobacco products manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Reports on February 22, 2018, and issued Acknowledgement letters to the applicant on February 28, 2018. FDA issued an Advice/Information Request (A/I) letter to request information needed to compose an Environmental Assessment on May, 15, 2018.

Product Name	SE Report
Husky Fine Cut Wintergreen	SE0014544
Husky Long Cut Straight	SE0014545
Husky Long Cut Mint	SE0014546
Husky Long Cut Natural	SE0014547
Husky Fine Cut Natural	SE0014548

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by Jessica Kiser on February 28, 2018.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated March 30, 2018, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated May 14, 2018, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following discipline:

4.1. CHEMISTRY

A chemistry review was completed by Selena Russell on April 5, 2018.

The chemistry review concludes that the new tobacco products have a different characteristic related to product chemistry compared to the corresponding predicate tobacco products, but the difference does not cause the new tobacco products to raise different questions of public health. The review identified the following difference:

- (b) (4) (non-GRAS) replaced with equal amount of (b) (4) (GRAS)

The applicant provided a certification statement signed by a responsible official authorized to act on behalf of the applicant stating that “the characteristics of the new and predicate product are identical in all aspects with the exception... replacement of non-GRAS (b) (4), (b) (4) in the predicate product with an identical amount of GRAS (b) (4) in the new product...” The only modification between the new and corresponding predicate products is the change in the flavor ingredient, non-GRAS (b) (4), (b) (4) to a GRAS (b) (4) with the exact same quantity (b) (4). Because the ingredient is going from non-GRAS to GRAS, the toxicity of the new products is expected to be no worse than the corresponding predicate products. Therefore, the difference in characteristics between the new and corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health related to product composition.

5. ENVIRONMENTAL DECISION

An environmental science review was completed by Shannon Hanna on April 25, 2018.

The final environmental review found that information regarding how the new and predicate products will be packaged was not provided, the marketing intention of the new and predicate product was not provided, and the Synthetic Minor Air Pollutant Source Operating Permit was expired. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The following is the only difference in characteristics between the new and corresponding predicate tobacco products:

- (b) (4) (non-GRAS) replaced with equal amount of (b) (4) (GRAS)

The applicant has demonstrated that this difference in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant provided a certification statement signed by a responsible official authorized to act on behalf of the applicant stating that “the characteristics of the new and predicate product are identical in all aspects with the exception... replacement of non-GRAS (b) (4) in the predicate product with an identical amount of GRAS (b) (4) in the new product...” The only modification between the new and corresponding predicate products is the change in the flavor ingredient, non-GRAS (b) (4) to a GRAS (b) (4) with the exact same quantity (b) (4). Because the ingredient is going from non-GRAS to GRAS, the toxicity of the new products is expected to be no worse than the corresponding predicate products. Therefore, the difference in characteristics

between the new and corresponding predicate products does not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco products are currently in compliance with the FD&C Act. In addition, the chemistry review concludes that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

However, FDA has reviewed the applicant’s environmental assessment (EA) and is requesting additional information to determine whether finding these new tobacco products substantially equivalent requires preparation of an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI). An inadequate resolution of this issue may delay or prevent issuance of SE order letters.

An Advice/Information Request letter should be issued requesting the following information:

1. All of your SE Reports lack detailed information about how the new and predicate products will be packaged, such as the packaging material used. Packaging materials would include such things as the can; display boxes that contain multiple cans; any liners, inserts, or overwrap in and on cans or display boxes; any shrink wrap; larger packaging for product distribution such as cartons holding multiple boxes; and any other packaging materials. This information allows for an accurate assessment of the solid waste generated from end use of the products. Address the following issues concerning the packaging:
 - a. Provide details as to how each retail unit is packaged, including details such as whether the cans are packaged in a box or shrink wrapped together, how many cans are packaged in a retail box and how many retail boxes are in a shipping case.
 - b. Provide the material types and weights of each packaging component of the new and predicate products in Table 1. If there are additional packaging components, add the appropriate lines to the table.

Table 1: Packaging Weight for New and Predicate Products			
STN	Package Component	Package Composition	Weight (grams)
SE0014544			
Predicate Product	Can		
	Can Lid		
	Label		
	Shrink Wrap		
	Retail Box		

Table 1: Packaging Weight for New and Predicate Products			
STN	Package Component	Package Composition	Weight (grams)
	Shipping Case		
New Product	Can	Polypropylene	9.0
	Can Lid	Polypropylene	3.8
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014545			
Predicate Product	Can		
	Can Lid		
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
New Product	Can	Polypropylene	9.0
	Can Lid	Polypropylene	3.8
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014546			
Predicate Product	Can		
	Can Lid		
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
New Product	Can	Polypropylene	9.0
	Can Lid	Polypropylene	3.8
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014547			
Predicate Product	Can		
	Can Lid		
	Label		
	Shrink Wrap		
	Retail Box		

Table 1: Packaging Weight for New and Predicate Products			
STN	Package Component	Package Composition	Weight (grams)
	Shipping Case		
New Product	Can	Polypropylene	9.0
	Can Lid	Polypropylene	3.8
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014548			
Predicate Product	Can		
	Can Lid		
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		
New Product	Can	Polypropylene	9.0
	Can Lid	Polypropylene	3.8
	Label		
	Shrink Wrap		
	Retail Box		
	Shipping Case		

2. All of your SE Reports lack information regarding the marketing intention of the predicate products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal of the new products as compared to the predicate products. Provide the following information:
 - a. Clearly state if the predicate products will be simultaneously marketed with the new products after the new products receive marketing orders.
 - b. If the predicate products are to be marketed simultaneously with the new products, provide the current market volume, and the first- and fifth-year market projections for the predicate products in Table 2.

Table 2: Predicate Products: Current and Projected Market Volumes				
Product	Unit	Current Market Volume	First-Year Projected Market Volume	Fifth-Year Projected Market Volume
Predicate of SE0014544	Cans			
Predicate of SE0014545	Cans			

Predicate of SE0014546	Cans			
Predicate of SE0014547	Cans			
Predicate of SE0014548	Cans			

3. All of your SE Reports include a Synthetic Minor Air Pollutant Source Operating Permit that expired December 31, 2017. A current permit shows compliance with environmental regulations. Provide a copy of the current permit.

If the applicant adequately responds to these requests and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0014544-SE0014548, as identified on the cover page of this review.